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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,428	10/14/2003	Mary Jo Mulligan-Kehoe	DC-0230	1865

7590 03/27/2006
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EXAMINER

HUYNH, PHUONG N

ART UNIT PAPER NUMBER

1644

DATE MAILED: 03/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/686,428	Applicant(s) MULLIGAN-KEHOE, MARY JO	
	Examiner Phuong Huynh	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE Three MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 2 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/22/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1 and 2 are pending.
2. In view of the amendment filed 12/22/05, the following rejection remains.
3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Mulligan-Kehoe et al (J Biochemical Chemistry 276(11): 8588-8596, March 2001; PTO 892).

Mulligan-Kehoe et al teach a method of making a 34 kDa truncated plasmin proteolytic protein (see page 8595, col. 2, third full paragraph, in particular). The reference method comprises combining rPAI-123 encoded by nucleotides 444-999 of porcine rPAI-1₂₃ (see page 8589, col. 1, paragraph 4, page 8589, col. 2, Materials and methods, in particular) or human rPAI-1₂₃ encoded by nucleotides 238-793 (see page 8589, col. 1, paragraph 4, in particular) and plasminogen (Plg) for 1 hour at 37°C, then adding single chain urokinase plasminogen activator (uPA) for an additional 1 hr at 37°C so that a truncated plasmin proteolytic protein product is produced; the truncated plasmin proteolytic protein has a molecular weight about 34 kDa (see page 8590, col. 2, first paragraph, in particular). Given the method steps and the reagents in the claimed method are the same as that of the reference as evidenced by the disclosure (see specification pages 60, 62 and 64) and the declaration of Mulligan-Kehoe filed on Dec 22, 2005, the reference method inherently produces the *same* product. The same product inherently recognizes by the same mini-plasminogen antibody. Since the Patent Office does not have the facilities for examining and comparing the claimed protein of the instant invention to those of the prior art, the burden is on applicant to show that the prior art antibody is different from the claimed antibody. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977). Thus, the reference teachings anticipate the claimed invention.

Applicants' arguments filed 12/22/05 have been fully considered but are not found persuasive.

Applicants' position is that while Mulligan-Kehoe et al. disclose a reaction containing plasminogen and PAI-1₂₃ with subsequent addition of uPA, this reference does not teach or suggest the nature of the uPA molecule. In contrast, Applicant has appreciated that a single chain uPA provides a 34 kDa truncated plasmin proteolytic protein, whereas two-chain UPA produces a slight upward shift in the molecular weight of the protein (see page 26, lines 5-12). Given the lack of such a side-by-side comparison in Mulligan-Kehoe et al., it is unclear whether the protein of Mulligan-Kehoe et al. represents the 34 kDa truncated plasmin proteolytic protein of the instant invention, which is recognized by a mini-plasminogen antibody, or the slightly larger protein disclosed in the specification.

In response, the specification at page 64, line 8-20 discloses two-chain urokinase plasminogen activator (uPA) is required for cleavage of plasminogen and two-chain uPA (tcuPA) were used (see page 64). Given the method steps and the reagents in the claimed method are the same as that of the reference as evidence by the disclosure (see specification pages 60, 62 and 64) and the declaration of Mulligan-Kehoe filed on Dec 22, 2005, the reference method inherently produces the *same* product. The same product inherently recognizes by the same mini-plasminogen antibody. Since the Patent Office does not have the facilities for examining and comparing the claimed protein of the instant invention to those of the prior art, the burden is on applicant to show that the prior art antibody is different from the claimed antibody. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

5. The following new ground of rejection is necessitated by the amendment filed 12/22/05.
6. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
7. Claims 1-2 are rejected under 35 U.S.C. 112, first paragraph, containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

The "single chain urokinase plasminogen activator" in Claim 1 represents a departure from the specification and the claims as originally filed.

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The specification at page 64, line 8-20 discloses two-chain urokinase plasminogen activator (uPA) is required for cleavage of plasminogen and two-chain uPA (tcuPA) were used. It would be helpful if applicant points out the support for "single chain urokinase plasminogen activator" in the specification and the claims as filed.

8. No claim is allowed.
9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The IFW official Fax number is (571) 273-8300.
11. Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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Phuong N. Huynh, Ph.D.

Patent Examiner

Technology Center 1600

March 17, 2006


CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600